PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 FEB 2006
WIPO PCT

Applicant's or agent's file reference 12505711	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/AU2004/001566	International filing date *(day/month/year)* 12 November 2004	Priority date *(day/month/year)* 14 November 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

A61M 27/00 (2006.01) ***A61F 9/007*** (2006.01)

Applicant

CORONEO, Minas Theodore

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[X]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23 February 2005	14 February 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **XAVIER GISZ** Telephone No. (02) 6283 2064

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001566

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1-16** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[X] the claims:

pages **13, 14** as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **15, 16** received by this Authority on **22 February 2005** with the letter of 17 February 2005
pages* received by this Authority on with the letter of

[X] the drawings:

pages **1/3 – 3/3** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   ☐ restricted the claims

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ neither restricted the claims nor paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

   The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

   1. Independent claims 1 and 10 are directed to a flexible ocular device comprising a foldable plate attached to the end of a tube wherein the foldable plate is located in the suprachoroidal space and the other end of tube opening to the anterior chamber. It is considered that a foldable plate located in the suprachoroidal space in fluid communication with the anterior chamber comprises a first "special technical feature".

   2. Independent claims 19 and 21 are directed to an ocular pressure spike shunt comprising a flexible transfer tube extending from the anterior chamber to the surface of the cornea. It is considered that a flexible fluid transfer tube extending from the anterior chamber to the surface of the cornea comprises a second special technical feature.

   These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is a flexible ocular device. However this concept is not novel in the light of US 2002/0087111 (ETHIER et al), US 5,752,928 (DE ROULHAC et al) and US 5,713,844 (PEYMAN). Therefore these claims lack unity *a posteriori*.

   The Attorney argues that another feature common to both inventions is maintaining a pressure of 10mm Hg. However since this feature is only present in some of the dependent claims, this cannot be considered a unifying feature.

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-21**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-21**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-21**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

Novelty (N) and Inventive Step (IS)

Claims 1-21 meet the criteria set forth in PCT Article 33(2) and 33(3) for novelty and inventive step. The prior art published before the priority date does not disclose or obviously suggest either of the following inventions as defined in the claims:

- a flexible ocular device comprising a foldable plate attached to the end of a tube wherein the foldable plate is located in the suprachoroidal space and the other end of tube opening to the anterior chamber.
- a temporary ocular pressure spike shunt comprising a flexible transfer tube extending from the anterior chamber to the surface of the cornea.

16. A method according to claim 10 wherein said tube has a length from 1 mm to 4 mm.

17. A method according to claim 10 wherein said tube comprises an outer diameter of 400-1000 μ and an inner diameter from 50 to 500 μ.

18. A method according to claim 13 wherein said valve comprises a slit valve.

19. An ocular pressure spike shunt for insertion into an ocular paracentesis incision port following ocular surgery, comprising a flexible fluid transfer tube formed of biocompatible material, preferably biocompatible elastomeric material, so as to allow paracentesis incision closure around said tube, having an inner end and an outer end, a tubular lumen disposed between said inner end and said outer end to allow fluid communication through said tube, said lumen containing a valve for controlling pressure in the eye following ocular surgery, which valve opens permitting fluid flow through said tube when a predetermined pressure is exceeded, said shunt being configured such that on insertion into a paracentesis port said outer end is substantially flush with the surface of the cornea, and said inner end opens into the anterior chamber of the eye, further wherein said shunt is adapted for removal from the ocular paracentesis incision port post-surgically.

20. A shunt according to claim 19 wherein said predetermined pressure is 10 mm Hg.

21. A method for preventing ocular pressure spikes following ocular surgery wherein a paracentesis incision port is formed in the eye during said surgery, comprising introducing an ocular pressure spike shunt into said paracentesis port at the conclusion of ocular surgery and removing said shunt post-surgically, said shunt comprising a flexible fluid transfer tube formed of biocompatible material, preferably biocompatible elastomeric material, so as to allow paracentesis incision closure around said tube, having an inner end and an outer end, a tubular lumen

disposed between said inner end and said outer end to allow fluid communication through said tube, said lumen containing a valve for controlling pressure in the eye following ocular surgery, which valve opens permitting fluid flow through said tube when a predetermined pressure is exceeded, said shunt being configured such that on insertion into a paracentesis port said outer end is substantially flush with the surface of the cornea, and said inner end extends into the anterior chamber of the eye, further wherein said shunt is adapted for removal from the ocular paracentesis incision port post-surgically.